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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,163	02/13/2002	Peter Thomas Lind	1718-0197P	9930

2292 7590 06/02/2003  
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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 06/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/076,163	LIND ET AL.
	Examiner	Art Unit
	Tamthom N. Truong	1624

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 5/5/63

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-30 is/are pending in the application.

4a) Of the above claim(s) 1-7, 29 and 30 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 8-28 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u>	6) <input type="checkbox"/> Other: _____

### **DETAILED ACTION**

Applicant's election with traverse of Group II (claims 8-28 (in part)) in Paper No. 5 is acknowledged. The traversal is on the ground(s) that there is no serious burden of searching as the "present set of claims was designed in accordance with the Restriction Requirement in the priority application 08/601,030...". This is not found persuasive because the original restriction requirement was done according to PCT Rule 13.1 which defines the unity of invention, and not burden of searching. An on-line search of group II does not yield references that read on other groups. Also, for "method of treatment" claims, there might be references that describe similar method of treatment in term of functional language, and could read on the claimed method. Thus, additional search is required.

The requirement is still deemed proper and is therefore made FINAL.

Claims 8-28 (in part) are considered herein while claims 1-7, 29, and 30 are withdrawn from consideration as being drawn to non-elected matter.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 11, 16, 18, 19, 25, and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a. Claims 11, 16, 19, and 25 misspell the word 'thienyl' as "theinyl" (in the definition of R<sub>1</sub>).
- b. Claims 16 and 25 lack antecedent basis because they recite the limitation of "N' linkage to R<sub>1</sub>...", which is not recited in the claims they depend on.
- c. Claim 18 lacks antecedent basis because it recites the limitation of "said agent is selected from...", which is not recited in claim 17. Note, claim 17 does not recite additional active agents.
- d. Claim 28 lacks antecedent basis because it is a composition claim but depend on claim 25, which is a compound claim. Besides, it also recites "wherein said at least one other therapeutic agent is...", which is not recited in claim 25. It appears that claim 28 should have been dependent on claim 27.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 2. **Scope of Enablement:** Claims 8-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the preparation of the claimed compounds, does not reasonably provide enablement for their use as antiviral agents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The following factors have been considered in the determination of an enabling disclosure:

- (1) The quantity of experimentation necessary;
- (2) The amount of direction or guidance presented;
- (3) The state of the prior art;
- (4) The relative skill of those in the art;
- (5) The predictability or unpredictability of the art;
- (6) The breadth of the claims;

[See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

Page 26 lists the IC<sub>50</sub> values for a few compounds; however, those compounds have R<sub>1</sub> as a **pyridyl** ring. Due to different ring structures, said IC<sub>50</sub> values cannot be extrapolated to compounds with R<sub>1</sub> as a thiazolyl, isothiazolyl, or thienyl ring. Because, the specification does not provide a correlation between the antiviral activity of pyridyl ring with that of other rings, one skilled in the art cannot predict the antiviral activity for compounds having R<sub>1</sub> as a thiazolyl, isothiazolyl, or thienyl ring. The state of the art, **Lind et. al.** (WO 93/03022), discloses antiviral activity for compounds having thiazole or isothiazole as a substituents. However, said compounds have the functional group of **thiourea**, which is not equivalent to those represented by the instant variable "A". Thus, one cannot rely on the teaching of Lind et. al. to confirm the antiviral activity for the claimed compounds.

Furthermore, the specification does not reveal a dosage for the claimed compounds.

Thus, in order to use the invention, one skilled in the art will have to carry out undue experimentation to first figure out which compound has antiviral activity, and then determine its therapeutic index as well as its pharmacokinetic profile.

Note, the "how to use" requirements of 35 USC 112 are not met by disclosing only a pharmacological activity of the claimed compounds if one skilled in the art would not be able to use the compounds effectively without undue experimentation. See **In re Diedrich**, 138 USPQ 128; **In re Gardner et. al.**, 166 USPQ 138. Thus, where the claimed compounds do not bear structures that are similar to known compounds having the same activity, and their pharmaceutical properties could not be predicted from their chemical structure, a disclosure that they possess a particular activity may not suffice as a description of how to use as required by 35 USC 112. See **In re Moureu et. al.** 145 USPQ 452. Note, the Federal Circuit has repeatedly held that "the specification must teach those skilled in the art how to make and use the **full scope** of the invention without 'undue experimentation'".

*References cited on PTO-892*

3. The references cited on PTO-892 disclose compounds of substituted isothiazolyl-urea. However, they are not competent prior arts because their effective filing dates do not antedate the effective filing date of this application.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485.

The examiner can normally be reached on M-F (9:30-5:00) & every Saturday morning (starting from 4-7-03).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



*Tamthom N. Truong*  
*Examiner*  
*Art Unit 1624*

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June 1, 2003